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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|------------------------------------|---------------------|------------------|
| 10/560,300 | 12/12/2005 | Jean-Paul Rene Marie Andre Bosmans | PRD2061USPCT | 2524 |
| 45511 | 7590 | 11/10/2008 | EXAMINER | |
| WOODCOCK WASHBURN LLP | | | CHANG, CELIA C | |
| CIRA CENTRE, 12TH FLOOR | | | | |
| 2929 ARCH STREET | | | ART UNIT | PAPER NUMBER |
| PHILADELPHIA, PA 19104-2891 | | | 1625 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/10/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/560,300 | BOSMANS ET AL. | |
| | Examiner | Art Unit | |
| | Celia Chang | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 July 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 10-13 is/are pending in the application.

4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7, 10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of group I in the reply filed on July 23, 2008 is acknowledged. The traversal is on the ground that all species are cyclic ethers and no burden in searching all structure (a-1) to (a-8).

It is unclear what is the "evidence" supporting the traversal. If the traversal is arguing that all (a-1) to (a-8) find similar structure, thus are obvious variants, then, if the examiner finds one of the (a-1) to (a-8) unpatentable over the prior art then all other structure of (a-1) to (a-8) would be rejected under 35 U.S.C. 103(a).

It is recommended that clarification of the traversal be made in the record.

The restriction is still deemed proper since no traversal was made between the compounds (group I) and method (group II).

Claims 1-7, and 10 reading on the elected species is prosecuted. Claims 8-9 have been canceled. Claims 11-13 are withdrawn from consideration per CFR 1.142(b).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

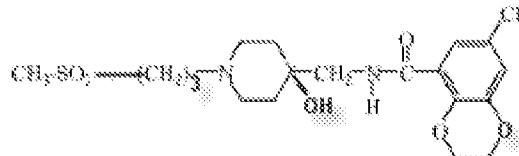
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosmans et al. US 6,544,997 in view of Lima et al. supplemented with Supuran et al., Chavatte et al. or Penning et al. further in view of Thominet et al. 4,186,135.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bosmans et al. '997 disclosed a species which is structurally close to the elected species as following:



See col. 43-44, compound 103.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art species and the instant elected species (compound 1, p.38) is that the L moiety of the prior species has a terminal substitution with CH_3SO_2^- , while the instant elected compound 1 has a H_2NSO_2^- substitution. Lima et al disclosed that CH_3SO_2^- and H_2NSO_2^- are bioisosteric modification, see p.27-28 compound 29-30, or Supuran et al. taught isosteric equivalency between CH_3SO_2^- and the H_2NSO_2^- see p.626 compound 5 vs 6. (Chavatte et al. or Penning evidenced that the discussion of Lima or Supuran are conclusive review of the prior art see especially Lima p.27 reference [19] dated 1997). The species further differ from the elected species in that the OH is at 4-position instead of 3-position of the piperidinyl ring and a chloro at the instant R4 position and a hydrogen at the instant R3 position. Thominet et al. '135 taught that in similar benzamidyl compounds, the substitution on the aromatic ring of the benzocyclic ether moiety can be optionally variations among the generically disclosed Markush elements (see col. 2, lines 18-43).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is well aware of all the pertinent art in the field. The above references placed the core structure and the optional choices of substituents within the possession of one having ordinary skill. The modification of a proven compound with a design choice of bioisosteric replacement of moieties (please note that the equivalency is well known in the prior art, the Lima or Supuran references provided state of the art discussion) is prima facie. Further, the other modification employing attributes of the other proven compounds in the prior art is prima facie obvious because Bosmans et al. '997 disclosed the optionally choices between 3-OH and 4-OH on the piperidinyl ring (see table F-3 and F3a) and the Thominet et al. '135 disclosed well delineated substitution pattern on the phenyl ring with exemplification from none to three substituents (see table I, especially col.39-40, X, Y and Z combinations) including R3 being amino (see compound 46), R4 being halo (compound 44-45). Applicants' elected species is the mere picking and choosing among the recognized substituents on the phenyl ring among the proven compounds.

3. Claims 1-7 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-8 of U.S. Patent No. 6,544,997 in view of Lima et al. supplemented with Supuran et al. ,Chavatte et al. or Penning et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the issued claims and the instant claims is the employment of a bioisosteric replacement of a terminal substituent on L (see generically, the instant R3 is halo and R4 is hydrogen).

4. Claims 1-7, 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of copending application No. 10/560,479 or claims 1-7, 10 of copending application No. 10/560,485, claims 1-7, 10 of copending Application No. 10/560,486 in view of Lima et al. supplemented with Supuran et al. ,Chavatte et al. or Penning et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because *prima facie* obvious subject matter are claimed. The elected species has L being -Alk-SO₂NH₂ while the copending claims have L being alkyl-X-R₇, X is SO₂, R⁷ is alkyl, thus, the bioisosteric replacement of the sulfonamide moiety.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 28, 2008

*/Celia Chang/
Primary Examiner
Art Unit 1625*